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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,681	06/27/2003	David Wynn	MCP-5016 NP	8293

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
BROWN, COURTNEY A	

ART UNIT	PAPER NUMBER
1616	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/608,681	WYNN ET AL.	
	Examiner	Art Unit	
	Courtney A. Brown	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

OFFICIAL ACTION

Acknowledgement of Receipt

Receipt of Applicant's Amendment filed on July 9, 2007 in response to an Office Action dated April 3, 2007 is acknowledged.

Status of Claims

Claims 9 and 16 were amended, and claim 6 was withdrawn, by an amendment filed on January 19, 2007. In addition, claims 1, 2, and 14 were amended, and claim 18-20 were added, by an amendment filed on July 19, 2007. As a result, claims 1-5 and 7-20 are currently pending and therefore examined herein on the merits for patentability.

Examiner's Response to Applicant's Remarks

Applicant's arguments filed on January 19, 2007 have been fully considered. Rejections and/objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections-35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the. claimed invention. Specifically, claim 13 lacks written description because while the claim and specification state that no more than a certain percent of water is left after drying at 105 °C, the time in which the dosage form is dried was not recited. Therefore, claim 13 lacks written description because the amount of water remaining after drying at high temperature would depend upon the time it was dried. Therefore, applicants have not described their limitation in the claims or specification in sufficient detail to practice their claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-5 and 7-17 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is hereby withdrawn in view of Applicant's amendments to the claims.

Claim 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically Claim 20 recites that the dosage form meets USP dissolution requirements for immediate release, but the claim does not describe how the requirement would be met, ie time of dissolution, percent of active released and the conditions of the test. Therefore since claim 20 does not describe how a USP dissolution requirement can be met the claim is indefinite.

Double Patenting

Claims 1-7 and 8-20 of this application conflict with claim 1-8, 10,12, 14, and 17-23 of Application No. 10/607,766. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg,* 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman,* 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi,* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum,* 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re*

Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7 and 8-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 10,12, 14, and 17-23 of Application No. 10/607,776. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would be obvious to one skilled in the art to coat the tablet with a taste masking coating with an enteric polymer selected from a group consisting of hydroxypropylcellulose as done in Application No. 10/607,776.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections- 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that

the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuter et al. (U.S. 4,835,187) in view of Dressman et al. (U.S. 5,789,393), and further in view of Siebert et al. (WO 00/09090).

Applicant's Invention

Applicant claims an oral immediate release dosage in the form of a tablet comprising: a.) a plurality of particles comprising a pharmaceutically active ingredient having a particle size of about 150-400μm selected from the group consisting of acetaminophen, acetyl salicylic acid, ibuprofen, naproxen, ketoprofen, flurbiprofen, diclofenac, cyclobenzaprine, meloxicam, rofecoxib, celecoxib, and pharmaceutically acceptable salts, esters, isomers, and mixtures

thereof and b.) a matrix (wherein the plurality of particles comprised of a pharmaceutically active ingredient are substantially free of hydroxyalkycellulose) comprising .1-25% hydroxypropylmethylcellulose having a weight average MW of from about 140,000 to about 1,150,000 Daltons and a viscosity of from about 3,000 mPa.S to about 150,000 mPa.S in a 2% aqueous solution and 50-80% of a water-disintegratable compressible carbohydrate selected from the group consisting of dextrose monohydrate, mannirtol, srobitrol, xylitol, and mixtures thereof. Applicant further limits the invention to being a dosage form that meets USP dissolution requirements for immediate release form of said pharmaceutically active ingredient and having a moisture content of not more than about 5% as measured by weight loss on drying at 105 degrees Celsius.

Determination of the scope and the content of the prior art (MPEP 2141.01)

Reuter et al. teach an immediate release composition in chewable solid dosage form comprising: a plurality of inert silica particles of about 10 millimicrons (i.e., 10 nm or 0.01 pm) comprising ibuprofen, which is present in an amount of from about 40 wt.% to about 70 wt.%; USP hydroxypropylmethylcellulose grades E, F and K (e.g., Methocel/HPMC E4MP)

having a viscosity ranging from about 3,500 centipoise to about 5,600 centipoise (i.e., from about 3,500 mPa.s to about 5,600 mPa.s) and present in an amount ranging from 15 wt.% to about 50 wt.%; and mannitol (abstract; column 1, lines 1-68; column 2, lines 1-68; column 3, lines 6-68; column 4, lines 6, 22 and 56-68; column 5, lines 1-9). Reuter et al. further teach incorporating the taste neutral ibuprofen powder in pharmaceutical dosage forms for oral administration (column 1, lines 45-61 and claims 1-9).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

Reuter et al. do not teach the composition comprising a matrix comprising the hydroxyproylmethylcellulose.

Dressman et al. teach that a 2% aqueous solution of a high molecular weight HPMC advantageous in the practice of the invention has a viscosity of about 30,000 mPa.S and that rheological studies have confirmed that a very high molecular weight HPMC of about 400,000 mPaS at 20 degrees Celsius in a 2% aqueous solution produces a viscosity equivalent to 30,000 cP at a concentration of 1.5% (column 19, lines 65 to column 20, lines 1-5).

Also, Reuter et al. do not teach the instantly claimed particle diameters ranging from about 150 μm to about 400 μm and the weight percentage of the

water-disintegratable compressible carbohydrate being from about 50 to about 80 percent.

Siebert et al. teach the use of microcapsules having a particle size ranging form between about 50 to about 3,000 microns (μm) (see page 4, lines 3-5). Additionally, Siebert et al. teach the use of 5-60% of a sugar or a sugar alcohol (page 4, lines 8-10). Siebert et al. list examples of sugar and sugar alcohols such as mannitol, sorbitol, and xylitol (see page 11, lines 23-26).

Finding of prima facie obviousness

Rationale and Motivation (MPEP 2142-2143)

It would have been obvious to a person having ordinary skill in the art at the time of the invention was made to combine the teachings of Reuter et al., Dressman et al., and Siebert et al to devise a tablet capable of being chewed or disintegrated in the oral cavity prior to swallowing. One would be motivated to combine these teachings because the claimed limitations on the molecular weight of hydroxyproylmethylcellulose would also have been obvious to one of ordinary skill in the art because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to anticipated success, it is likely the product not of innovation but of ordinary

skill and common sense. Thus since the use of hydroxyproylmethylcellulose within applicants claimed MW range was already well known to be useful in pharmaceutical compositions as shown by Dressman, applicant's claimed hydroxyproylmethylcellulose was a known option available at the time of the invention and someone of ordinary skill in the art would have a high expectation of success using the specific MW of hydroxyproylmethylcellulose disclosed. This is also true for claimed particle diameters and the weight percentage of the water-disintegratable compressible carbohydrate as taught by Siebert et al.

It would be prima facie obvious to combine compositions each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for the very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." In re Kerkhoven 206 USPQ 1069, 1073. Thus, combining Reuter et al. with Dressman and Siebert et al., as claimed in the instant invention, sets forth prima facie obvious subject matter.

Contact Information

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public

PAIR. Status information for unpublished applications is available through Private PAIR Only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electron Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Courtney Brown, whose telephone number is 571-270-3284. The examiner can normally be reached on Monday-Friday from 8 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

SHELLEY A. DODSON
PRIMARY EXAMINER

Courtney A. Brown
Patent Examiner
Technology Center1600
Group Art Unit 1616

Johann R. Richter
Supervisory Patent Examiner
Technology Center 1600
Group Art Unit 1616